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5 AUTOMATED LASER WORKSTATION FOR HIGH PRECISION SURGICAL AND
 INDUSTRIAL INTERVENTIONS

SPECIFICATION

Reference to Related Applications

5 This application is a continuation-in-part of copending patent appli-
cation Serial No. 307,315, filed February 6, 1989; *now*
and copending application Serial No. 475,657, filed February 6, 1990,

Background of the Invention

15 The invention relates to methods and apparatus for performing pre-
cise laser interventions, and in particular those interventions relevant to
improved methods and apparatus for precision laser surgery. In one pre-
ferred embodiment, the system of the invention is used for effecting pre-
cise laser eye surgery. In other embodiments the invention is applicable to
non-surgical diagnostic procedures or non-medical procedures involving
precision laser operations, such as industrial processes.

30 When performing laser interventions, whether in medical surgery,
industrial processes, or otherwise, several fundamental considerations
are common to most applications and will influence the viability and ef-

fectiveness of the intervention. To influence the outcome of the intervention, the present invention addresses both the technical innovations involved in an apparatus to facilitate precision laser interventions, and the methods by which a user of such apparatus can achieve a precise result.

The present invention addresses the following considerations: (1) how does the user identify a target for the laser intervention, (2) how does the user obtain information as to the location and other pertinent features of the target and its important surroundings, (3) how does the user lock onto that target so that the user has the assurance he is affecting the intended target, (4) how does the user localize the effect to the target site, (5) how does the user treat a large number of individual targets, whether continuously connected, piecewise connected, or disconnected, (6) how does the user assess the effect of the intervention, (7) how does the user correct errors committed either during the course of the intervention or as a result of previous interventions, (8) how does the user react to changing conditions during the course of the intervention to ensure the desired result, and (9) how is safety ensured consistent with U.S. Food and Drug Agency regulations for medical instruments and good commercial practice guidelines for industrial applications.

Of particular interest are medical interventions such as surgical procedures described by Sklar et. al. (U.S. patent applications Serial Nos. 307,315 and 475,657, which are incorporated herein by reference). Although many different kinds of surgery fall within the scope of the pres-

ent invention, attention is drawn to corneal refractive surgery in ophthalmology for the treatment of myopia, hyperopia, and astigmatism.

For corneal refractive surgery, the above nine considerations reduce
5 to the following objectives (in accordance with the present invention described below): (1) identify the location on or in the cornea to be treated, (2) assure that the target is at the desired distance from the apparatus, determine the topography of the cornea, and determine the location of sensitive tissues to be avoided, (3) identify, quantify, and
0 pursue the motion of suitable part of the cornea which can provide a reference landmark that will not be altered as a result of the surgical intervention and, likewise, the depth variations (for example, distance from the corneal surface to the front objective lens changing due to blood pressure pulses) of the corneal surface with respect to the apparatus such
5 that said motions become transparent to the user of the apparatus, (4) provide a laser beam which can be focused onto the precise locations designated by the user such that peripheral damage is limited to within tolerable levels both surrounding the target site and along the laser beam path anterior and posterior to the target site, (5) provide a user interface
10 wherein the user can either draw, adjust, or designate particular template patterns overlaid on a live video image of the cornea and provide the means for converting the template pattern into a sequence of automatic motion instructions which will traverse the laser beam to focus sequentially on a number of points in three dimensional space which will in turn
15 replicate the designated template pattern into the corresponding surgical intervention, (6) assure that items (1)-(3) above can be performed contin-

uously during the course of and subsequent to the surgery to monitor the evolution of the pertinent corneal surface and provide a means of accurate comparison between pre-operative and post-operative conditions, (7) ensure that the structural and physiological damage caused by the surgery to the patient is sufficiently small to permit continued interventions on the same eye, (8) automate the interaction between the various components so that their use is transparent to the user and so that sufficiently fast electronics accelerate completion of the surgical intervention within preselected error tolerances, and (9) provide dependable, fail-safe safety features of sufficiently short reaction times to prevent any chance of injury to sensitive corneal tissues. With these objectives fulfilled, the speed of surgery will no longer be limited by human perception delay and response times but by the capability of the apparatus to recognize changing patterns and adjust to the new conditions. Equally important, the accuracy of the surgery will not be constrained by the bounds of human dexterity, but by the mechanical resolution, precision, and response of advanced electro-optical and electromechanical systems.

There are a substantial number of different functions which the apparatus of the present invention addresses. Each of the complementary, and at times competing, functions requires its own technologies and corresponding subassemblies. The present invention describes how these various technologies integrate into a unified workstation to perform specific interventions most efficaciously. For example, for corneal refractive surgery, as per (1) and (2) above, to identify the location to be treated on or in the cornea, the surgeon/user would use a combination of

video imaging and automated diagnostic devices as described by Sklar et. al. (U.S. patent applications Serial Nos. 307,315 and 475,657), depth ranging techniques as described by Fountain (U.S. patent application Serial No. 655,919), ^{filed February 19, 1991} surface topographical techniques, as described by Sklar (U.S. patent No. 5,054,907) together with signal enhancement techniques for obtaining curvatures and charting the contours of the corneal surface as described by McMillan and Sklar (U.S. patent application Serial No. 656,72-2), ^{filed February 19, 1991} profilometry methods as disclosed by McMillan et. al. (copending U.S. patent application Serial No. _____, referred to heretoeafter as 266P, and entitled "Illumination of the Cornea for Profilometry," which was filed on the same date and assigned to the same party as the present application), image stabilization techniques as described by Fountain (U.S. Patent Application Serial No. 655,919), which may all be combined using techniques as described by Sklar et. al. (U.S. Patent Applications Serial Nos. 307,315 and 475,657). All of the above listed patent applications and the patent of Fountain (U.S. patent application Serial No. 833,604 ^{filed 2/11/92}), are herein incorporated by reference.

Aspects of the above referenced disclosures are further used to provide means of satisfying the key aspects (3) through (9) noted above, such as verification of target distance from the apparatus, tracking the motion of the cornea in three dimensions, providing a laser whose parameters can be tuned to selectively generate photodisruption of tissues or photocoagulation as desired, automatically targeting and aiming the laser beam to precise locations, and supplying a surgeon/user with a relatively simple means of using the apparatus through a computer interface.

It is well known that visible light, which is passed without significant attenuation through most ophthalmic tissues, can be made to cause a plasma breakdown anywhere within eye tissue whenever the laser pulse can be focused to sufficiently high irradiance and fluence levels to support an avalanche process. The ensuing localized photodisruption is accomplished by using a strongly focussed laser beam such that only in the immediate focal zone is the electric field sufficiently strong to cause ionization and nowhere else. By using short pulses of controllably small laser energy, the damage region can be limited in a predictable manner while still guaranteeing the peak power necessary for localized ionization.

Furthermore, with lasers of increasingly higher repetition rate becoming available, the sometimes intricate patterns desired for a given surgical procedure can be accomplished much faster than the capabilities of a surgeon manually to aim and fire recursively. In prior systems and procedures, the surgeon would aim at a target, verify his alignment, and if the target had not moved, then fire the laser. He would then move on to the next target, and repeat the process. Thus, the limiting factor to the duration of the operation under these prior procedures was the surgeon's reaction time while he focussed on a target and the patient's movement while the surgeon found his target and reacted to the target recognition by firing the laser. In practice, a surgeon/user can manually observe, identify, move the laser focus to aim, and fire a laser at not more than two shots per second.

By contrast, a key object of the instrument and system of the present invention is to stabilize the motion of the patient by use of an automated target acquisition and tracking system which allows the surgeon to predetermine his firing pattern based on an image which is automatically stabilized over time. The only limitations in time with the system of the present invention relate to the repetition rate of the laser itself, and the ability of the tracking system to successfully stabilize the image to within the requisite error tolerances for safety and efficacy, while providing a means to automatically interrupt laser firing if the target is not found when a pulse is to be fired. Thus, where it would take several hours for a surgeon/user to execute a given number of shots manually (ignoring fatigue factors), only a few minutes would be required to perform the same procedure when automatic verification of focal point position and target tracking are provided within the device.

It is an object of the present invention to accommodate the most demanding tolerances in laser surgery, particularly eye surgery but also for other medical specialties, through a method, apparatus and system for high-precision laser surgery which provides the surgeon "live" video images containing supporting diagnostic information about depth and position at which a surgical laser will be fired. In a computer, the full information content of a given signal is interpreted so as to provide this supporting diagnostic information, and the resulting accuracy achievable is within a few human cells or better.

The system, apparatus, and method of the present invention for precision laser surgery, particularly ophthalmic surgery, take a fully integrated approach based on a number of different instrumental functions combined within a single, fully automated unit. For example, previous
5 conventional diagnostic instruments available to the ophthalmic surgeon have included several different apparatus designed to provide the surgeon/user limited measurement information regarding the cornea of the eye, such as the corneoscope, the keratometer, and the pachymeter. The corneoscope provides contour levels on the outer surface of the cornea, or cor-
0 neal epithelial surface, derived, typically, from projected concentric illumination rings. The keratometer gives cross sectional curvatures of the epithelial surface layer resulting in an estimation of the diopter power of the front surface lens of the eye -- the corneal epithelium surface. Only one group of points is examined, giving very limited informa-
5 tion. Pachymeters are used to measure the central axial thicknesses of the cornea and anterior chamber.

The diagnostic functions fulfilled by these devices are instrumental to characterizing the subject tissue in sufficient detail to allow the sur-
20 geon to perform high precision ophthalmic surgery. Unfortunately, these and other similar instruments require considerable time to operate. Further, their use required near-total immobilization of the eye or, alternatively, the surgeon/user had to be satisfied with inherent inaccuracies; the immobilization methods thus determined the limitations on the accu-
25 racy and efficacy of eye surgery. Nor did the different apparatus lend themselves to being combined into one smoothly operating instrument.

For all of the above reasons, operation at time scales matched to the actual motions of the tissues targeted for therapy and/or limited by the fastest human response times to these motions ("real time") has not been possible with any of the conventional instruments used to date.

By contrast, the methods and apparatus disclosed herein, aim to incorporate a mapping and topography means for reconstructing the corneal surface shape and thickness across the entire cornea. It is furthermore within the scope of the present invention to provide such global measurements of the corneal refractive power without sacrificing local accuracies and while maintaining sufficient working distance between the eye and the the front optical element of the instrument (objective lens), said measurements to be executed on-line within time scales not limited to human response times. Most standard profilometry techniques were judged inadequate per the above requirements, requiring compromises in either accuracies of the computed curvatures (such as, e.g., standard 'k' readings of keratometers), speed and ease of operation (scanning confocal microscopes) or left no working distance for the ophthalmologist (corneoscopes and keratoscopes based on "placido disk" illumination patterns). It is therefore a key objective of the present invention to include a new topography assembly that can overcome the limitations of existing instruments while combining, on-line, and in a cost effective manner, many of the functions of conventional diagnostic instruments presently available to the surgeon, as an integral part of a complete surgical laser unit.

In one embodiment of the present invention, the corneal refractive power is measured using a unique projection and profilometry technique coupled with signal enhancement methods for surface reconstruction as disclosed by McMillan and Sklar in U.S. patent application Serial No. 656,722 and further extended to larger corneal cross-sections via techniques described by McMillan et. al. in copending U.S. patent application Serial No. , (per ref. 266P as cited above). In another embodiment, digitized slit lamp video images are used to measure the local radii of curvature across the entire corneal surface as well as the thickness of the cornea, with no built-in a-priori assumptions about the corneal shape. Both embodiments of the topography system benefit greatly from the availability of a 3D tracking capability contained within the apparatus. This feature allows elimination of many of the errors and ambiguities that tend to compromise the accuracy of even the best currently available instruments utilizing fine point edge extraction and advanced surface fitting techniques. With the computerized topographic methods of the present invention, surfaces can be reconstructed (and viewed in three dimensions) with accuracies that go well beyond the approximate photokeratometric and pachometry readings as advocated by L'Esperance (U.S. patent No. 4,669,466), or even the more sophisticated (but complex) corneal mapping methods as disclosed by Bille (U.S. patent application Serial No. 494,683) ^{now} and Baron (U.S. patent No. 4,761,071).

While tissue topography is a necessary diagnostic tool for measuring parameters instrumental to defining templates for the surgery (e.g., refractive power), such instrumentation is not conducive to use during sur-

gery, but rather before and after surgery. Also, the information thus obtained is limited to those parameters characteristic of surface topography (such as radii of curvature of the anterior and/or posterior layers of the cornea or lens). Yet, in many cases, it is desirable to simultaneously
5 image the target area and deposit laser energy at a specific location within the tissue itself. To allow reliable, on-line monitoring of a given surgical procedure, additional mapping and imaging means must therefore be incorporated. The imaging means is intended to record, in three dimensions, the location of significant features of the tissue to be operated
0 upon, including features located well within the subject tissue. It is therefore another object of the present invention to provide continuously updated video images to be presented to the surgeon/user as the surgery progresses, said images to be produced in a cost effective manner yet compatible with high resolution and high magnification across a large
5 field of view and at sufficiently low illumination levels to prevent any discomfort to the patient.

The imaging system, or the surgical microscope, requires viewing the reflected light from the cornea, which has two components: (a) specular
20 lar (or mirror) reflection from a smooth surface, which returns the light at an angle opposite the angle of incidence about the normal from the surface and also preserves the polarization of the incident beam, and (b) diffuse reflection, in which light returned from a rough surface or inhomogeneous material is scattered in all directions and loses the polarization
25 of the incident beam. No surface or material is perfectly smooth or rough; thus all reflected light has a specular and a scattered component. In

the case of the cornea there is a strong specular reflection from the front surface/tear layer and weak scattered light from the cellular membranes below. Various standard 'specular microscopes' have been used to suppress the front surface reflection. We have chosen a combination of techniques: some aim at observing the combined reflections without differentiating between specular or diffuse signals (for operations at or in immediate proximity to the surface of the cornea); in others the surface is illuminated with polarized light, with the reflected images then microscopically viewed through a crossed polarizer for operation within deeper layers, after selectively filtering the more anterior reflections. A rejection of the polarized component can thus be achieved, greatly enhancing resolution at low enough light levels to prevent any discomfort to the patient. In either embodiment, the imaging system contained within the apparatus of the invention represents a significant improvement over standard "slit lamp" microscopes such as are in use with most ophthalmic laser systems.

Other efforts at imaging the eye, such as performed with a Heidelberg Instruments Confocal Microscope, or as described by Bille (U.S. patent No. 4,579,430), either do not lend themselves to inclusion as part of an on-line, cost effective, integrated surgical system (for the former), or rely upon scanning techniques which do not capture an image of the eye at a given instant in time (for the latter). The method of the present invention benefits from having an instantaneous full image rather than a scanned image; for full efficacy, the method does, however, require that the targeted area be stabilized with respect to both the imaging and the laser

focal region, so as to enhance the accuracy of laser deposition in tandem with the viewing sharpness.

Tracking is therefore considered a critical element of a system
5 designed not only to diagnose, but to also select treatment, position the
treatment beam and image the tissue simultaneously with the treatment,
while assuring safety at all times. In the case of corneal surgery, move-
ments of the eye must be followed by a tracking system and, using dedi-
cated microprocessors, at closed-loop refresh speeds surpassing those
0 achievable by unaided human inspection, by at least an order of magnitude.
Tracking by following the subject eye tissue, i.e., recognizing new loca-
tions of the same tissue and readjusting the imaging system and the sur-
gical laser aim to the new location, assures that the laser, when firing
through a prescribed pattern, will not deviate from the pattern an unac-
5 ceptable distance. In preferred embodiments of the invention, this dis-
tance is held within 5 microns in all situations during ophthalmic surgery,
which sets a margin of error for the procedure. It is possible that with
future use and experimentation, it may be found that either more stringent
or alternatively more lax displacement error tolerances are desirable to
20 improve overall system performance.

Stabilization of a moving target requires defining the target, char-
acterizing the motion of the target, and readjusting the aim of the appara-
tus of the present invention repeatedly in a closed-loop system. To meet
25 accuracy goals also requires that the moving parts within the apparatus
not contribute internal vibrations, overshoots, or other sources of posi-

tioning error which could cumulate to an error in excess of the prescribed mispositioning tolerances. There have been several previous attempts at achieving this result. Crane and Steele (Applied Optics, 24, p. 527, 1985) and Crane (U.S. patent No. 4,443,075) describe a dual Purkinje projection technique to compare the displacement of two different-order Purkinje projections over time, and a repositioning apparatus to adjust the isometric transformation corresponding to the motion. The tracking methods disclosed therein are based on a fundus illumination and monitoring device that aspires to distinguish translational from rotational eye movements, thus stabilizing an illuminating spot on the retina. However, localization of the Purkinje points can be influenced by transient relative motions between the various optical elements of the eye and may provide significantly fictitious position information for identifying the surface of the cornea. Motility studies as described by Katz et al. (American Journal of Ophthalmology, vol. 107, p. 356-360, "Slow Saccades in the Acquired Immunodeficiency Syndrome", April 1989) analyze the translations of an image on the retina from which the resulting coordinate transformation can be computed and galvanometric driven mirrors can be repositioned. In addition to the fictitious information discussed above due to relative motions between different layers of the eye, the galvanometer drives described by Katz usually are associated with considerable overshoot problems. Since saccades can be described as highly accelerated motions with constantly changing directions, overshoot errors can easily lead to unacceptable errors.

Bille et. al. (U.S. Patent 4,848,340) describes a method of following a mark on the epithelial surface of the cornea, supposedly in proximity of the targeted surface material. However, in one of the uses of the present invention, a mark made on the epithelial surface would change its absolute location due to changes in the structure and shape of the material, caused by use of the instrument itself rather than by eye motions. Therefore, a target tracking and laser positioning mechanism that relies on a mark on the surface of the cornea in order to perform corneal surgery such as described by Bille's tracking method would be expected to lead to misdirected positioning of laser lesions below the surface when combined with any suitable focussed laser, as intended in one of the uses of the present invention. Moreover, one of the features of the present invention is to be able to perform surgery inside the cornea without having to incise the cornea. The main advantages of such a procedure are in avoiding exposure of the eye to infection and in minimizing patient discomfort. It would hence be counterproductive to mark the surface of the cornea for the purpose of following the motion of said mark. In another embodiment taught by Bille et. al., the tracking is based on a reference provided by either on the eye's symmetry axis, or the eye's visual axis, with an empirically determined offset between the two. Tracking is then accomplished by monitoring the reflection from the apex of the cornea, thus avoiding the need to mark the eye, and/or rely solely on patient fixation. However, with this technique, as in the preferred embodiment taught by Bille et. al., the tracking does not follow tissue features generally at the same location as the targeted surgical site on or inside the eye. Instead, Bille et. al.'s techniques track reference points that are, in all cases, separate, remote

from and may be unrelated to the targeted surgical site. Such methods compromise accuracy of tracking in direct proportion to the degree of their remoteness relative to the surgical site. Therefore, they do not adequately provide for the fact that the eye is a living tissue, moving and changing shape to some extent constantly. Tracking a single point on the cornea, when the cornea itself actually shifts considerably on the eye, thus cannot be expected to reflect positional change of the targeted surgical site.

By contrast, in the preferred embodiment of the present invention the tracking information is obtained through means contiguous to the target region, which is mechanically and structurally considered as part of the cornea, but is unlikely to be affected by the course of the surgery and can thus provide a significant representation of non-surgically induced displacements. This is a critical feature of the tracking method disclosed herein, in that involuntary motions of the eye (such as are caused by blood vessel pulsing) can now be accurately accommodated, unlike techniques that rely on remote reference points.

The accuracy of the apparatus and system of the invention preferably is within 5 microns, as determined by a closed-loop system which incorporates actual measurement of the target position within the loop. (For example, a microstepper motor based assembly may have a single step resolution of 0.1 micron verified against a motor encoder, but thermal gradients in the slides may yield greater variations. Moreover, position of the slide can be verified via an independent optical encoder, but

the random vibrations of the target can invalidate the relative accuracy of the motor.) Thus, the surgeon has knowledge of the shape of tissues within the field of view and the precise location of where he is aiming the instrument within those structures, to an accuracy of 5 microns. Such
5 precision was not attainable in a systematic, predictable manner with any of the prior instruments or practices used. The present invention thus seeks to obviate the need for binocular vision used to obtain stereoptic images in some prior methods (see, e.g., Crane, U.S. Patent 4,443,075).

0 In a preferred embodiment of the invention, the instrument also ensures that a laser pulse is fired only upon command of the computerized controller and after the system has verified that the tracking assembly is still locked onto the desired location, that the energy being emitted by the laser falls within prescribed error tolerances, and that the aiming and
5 focussing mechanisms have reached their requested settings. There is no need for a separate aiming beam. In one embodiment of the present system, the method of parallax ranging is implemented to map out surfaces posterior to the cornea, but preceding actual treatment.

10 Safety is a very important consideration with laser surgery. In prior surgical systems and procedures, some safety shut off procedures for laser firing have depended upon human reaction time, such as the use of a surgeon's foot pedal for disabling the instrument when a situation arises which would make firing unsafe. In ophthalmology, some instruments have
15 relied as a safety feature on a pressure sensor located where the patient's

forehead normally rests during surgery. If insufficient pressure were detected by the sensor, the instrument would be disabled from firing.

Such prior safety systems have inherently had slow reaction times, and have not been able to react quickly enough to all of the various problems which can arise during a firing sequence. This is a critical concern in ophthalmic surgery, especially where specific surgical procedures are to be performed near sensitive non-regenerative tissues such as the corneal endothelium layer and the optic nerve. In contrast, the target capture and tracking system of the present invention makes available a new and highly dependable safety system. If for any reason, either prior to or during a given surgical procedure, the tracking system loses its target, the laser is disabled from firing. Various options are available for blocking emission from the apparatus once the tracking assembly has verified the loss of a tracking signal.

No previous surgical laser system has employed the efficacious combination of features as disclosed herein. For example, in previous art, Bille et. al. (U.S. Patent No. 4,848,340) and Crane (U.S. Patent No. 4,443,075) taught tracking techniques to follow tissue movements which might occur during surgery, but did not teach simultaneous 3D imaging within the tissue to monitor the effects of surgery on the tissue and provide requisite safety margins; L'Esperance (U.S. Patent Nos. 4,669,466 and 4,665,913) also did not suggest any aspects of 3D imaging, teaching only laser surgery on the anterior surface of the cornea; Bille (U.S. Patent No. 4,579,430) shows a retina scanner but does not teach simultaneous

tracking. Bille et. al. (U.S. Patent No. 4,881,808) teach an imaging system and incorporate a tracker and a beam guidance system by reference (per U.S. patents Nos. 4,848,340 and 4,901,718, respectively) but fail to address the very difficult challenges involved in achieving a smooth combination of all these aspects into a single surgical laser unit with built-in high reliability features. By contrast, it is the unique integration of several such diverse aspects (including mapping, imaging, tracking, precision laser cutting and user interface), precisely yet inexpensively, into a fully automated workstation, the uses of which are transparent to the user, that is the main subject of the present invention. The methods and apparatus disclosed herein are thus expected to enhance the capabilities of a surgeon/user in accomplishing increasingly more precise surgical interventions in a faster and more predictable manner. Enhanced safety is expected to be a natural outcome of the methods and apparatus taught herein in that the surgery will be performed without many of the risks associated with competing methods and apparatus such as described by L'Esperance (U.S. Patent Nos. 4,669,466 and 4,665,913), Srinivasian (U.S. Patent No. 4,784,135), Bille et. al. (U.S. Patent No. 4,848,340, 4,881,808 and 4,907,586), Frankhauser (U.S. Patent No. 4,391,275), Aron-Rosa (U.S. Patent No. 4,309,998), Crane (U.S. Patent 4,443,075) or others.

Summary of the Invention

An embodiment of the present invention is herein disclosed, comprising a method, apparatus, and system for precision laser based micro-
5 surgery or other laser based micromachining, and including the following elements, each of which is described below.

(1) A final objective (lens), the axial position of which relative to the tear layer of the corneal vertex (or to a more general target), is held
0 constant by an axial tracking means, and through which pass all optical radiations emitted or accepted by the system. (2) An axial tracking means (including associated optics) for maintaining constant separation between the final objective and its target (which is to be distinguished from the (common) target for the treatment means and the parallax ranging means,
5 and also from the target for the viewing means) as that target moves axially along the final objective's centerline. The axial tracking means includes a compensation means to preclude it from being adversely affected by the transverse tracking means. (3) A transverse tracking means (including optics) for maintaining constant aiming between the treatment
10 and parallax ranging means and their (common) target, and between the viewing means and its target, as those targets move (together) transversely to the final objective's centerline. (4) A treatment means for effecting the actual laser microsurgery/micromachining, including a laser, laser-beam directing optics, a treatment aiming means (with optics),
15 and a treatment focussing means (also including optics), all of which are actuated by a computerized control means. (5) A parallax ranging means,

which shares optics for the treatment aiming and focussing means, for positioning the common focus of the treatment and parallax ranging means at a desired location (independent of the targets identified above) by use of the viewing means and without requiring the actual operation to be performed. (6) A viewing means, comprising optics and a low-light-level TV camera, for presenting to the surgeon/user, on the display means, an adjustably magnified image of the volume adjacent to the viewing target, which target may be chosen by the user independently of the other targets identified above. (7) A computerized control means, including a user interface presented on the display means, which performs calculations and accepts and issues signals in order to execute the various functions of the overall system. (8) A display means for presenting to the surgeon/user the image from the viewing means plus computer-generated overlays from the user interface; such overlays include not only menus but also textual and graphic representations of aspects such as the topography of the cornea (or more general surfaces associated with the various targets) and the microsurgery/micromachining template to be used. (9) A profiling means, including optics, one or more (patterned) profilometry illuminators, and a TV camera, to generate the data from which the computerized control means can calculate the topography of the cornea (or, in other embodiments, a more general surface). (10) An output measurement means to measure parameters of the laser radiation delivered to the eye of the patient or the workpiece. (11) Various illumination means, such as the profilometry illuminators, the coaxial illuminator, and the slit illuminator, to provide the light source(s) for the profilometry means, the transverse tracking means and the viewing means.

The present invention is expected to be useful in a variety of medical specialties, especially wherever the positioning accuracy of laser lesions is critical and where accurate containment of the spatial extent of a laser lesion is desirable. Much of the following discussion will be directed at ophthalmic applications and specifically corneal refractive surgery. This should not be viewed as a limitation on the applicability of the apparatus and method of the present invention. Alternate embodiments of the invention are expected to play a role in several other medical applications.

The system is also useful for non-medical operations, such as industrial operations, especially micromachining and short repair of microchips, wherein a focused laser beam is used to perform high precision operations on an object subject to movement, or in the automated inspection and correction of errors in the manufacture of microprocessors and high density integrated circuits.

In a specific application to corneal procedures, the present invention is intended to provide a means by which an ophthalmologist can (a) observe the patient's eye at both low magnification to orient the procedure and at progressively higher magnification to provide greater resolution for finer and more accurate procedures, (b) access on-line diagnostic information as to the shape of one or more relevant surfaces or of tissue layers to be treated, (c) describe a pattern of shots to effect a particular lesion shape without requiring manual aiming of each shot by the surgeon,

- (d) provide a therapeutic laser beam propagating through a beam steering and focussing delivery system which can localize the laser lesions at a particular depth in the immediate neighborhood of the laser focal point without appreciable damage elsewhere and with minimal peripheral necrosis or thermal damage surrounding the affected volume, and (e) provide
- 5 a target tracking system that can minimize the error in positioning the pattern of the laser lesion in a moving target.

In the user interface, a video monitor screen is provided in front of the surgeon, and the screen provides a variety of choices for imaging and diagnostic information. Among the selections available to the ophthalmologist, for example, is a live video image of the eye superimposed over sectional perspectives of the shape of the corneal anterior surface and displayed along with the location where the proposed surgical lesion is

5 situated. Another choice is to display a wire-mesh contour elevation map of said corneal surface together with an imbedded display of the proposed lesion. These selections can all be enlarged by using the zoom option which augments the live video image, and proportionally also the wire-mesh surface contours, the perspective views of the surface, and all other

10 relevant diagnostics.

Additionally, a library of patterns is available so that the computer can generate templates based on the optical correction prescribed (generated off-line by the physician's "refraction" of the patient) and the measured topography (which templates will automatically correct for edge

15 effects, based on built-in expert-system computational capability). The

surgeon/user can move the templates on the screen by means of a trackball, mouse, or other standard pointing device for manipulating points on a video screen and thus define the shape of the desired lesion and situate it at the optimal treatment location. These templates serve the additional function, once finally approved by the surgeon/user, of automatically controlling the path of the firing of the laser as well as the size and location of the laser-generated lesions to be formed in the course of the microsurgery. Since particular templates can be stored in computer memory, the surgeon may, as experience with the apparatus develops, draw on a bank of prior knowledge relating to a particular form of microsurgery, such as ophthalmic surgery directed to a specific type of correction. A physician may therefore choose to select from a set of pre-existing templates containing his preferred prescriptions, lay the template, in effect, on the computer-generated image of the region, and re-size and/or re-scale the template to match the particular patient/eye characteristics. The surgery can then be executed automatically in a precisely controlled manner, based on the computer programming sense.

Such a pre-existing library of templates is also useful in the execution of controlled animal studies. It should be noted, however, that without the accompanying three-dimensional targeting capability and the automatic image stabilization means contained within the hardware of the present invention, the utility of template-generated surgery alone would be severely limited either to non-sensitive tissues (where high three dimensional precision is not usually a consideration) or to relatively sta-

tionary or immobilized targets (not usually available at high magnification in a biological system which is "alive").

5 In other embodiments of the methods and hardware of the present invention, templates can also be generated and stored in similar manner for procedures other than cornealrefractive surgery, including iridotomy, posterior capsulotomy, trabeculoplasty, keratotomy, and others.

0 Among the advantages of the present invention is the modular design of the multiple assemblies. The multiple assemblies are each individually supported on kinematic mounts. These mounts allow for the separate construction of the multiple assemblies, their alignment to tooling jigs individually, and the precise "hard-aligning" of the multiple assemblies into a complex optical system. Although such kinematic mounts can add, 5 somewhat, to manufacturing cost, they save considerable alignment time during the assembly of the apparatus and provide a greater measure of reliability that the apparatus shall remain in operational alignment during continued use by non-technical surgeon/users.

10 Using the instrument of the present invention, the surgeon can generate a proposed pattern of therapeutic treatment, can compare the pattern to the actual tissues targeted, can compare his proposed surgery with what other surgeons have done in similar situations, and can still have the assurance that when he is finally satisfied with the proposed procedure, 15 he can push a button to cause the desired surgery to be carried out at

a high rate of independently targeted shots per second. This speed minimizes the risk during surgery of catastrophic patient motion.

5 In addition, the surgeon has at his disposal a fast reliable safety means, whereby the laser firing is interrupted automatically, should any conditions arise to warrant such interruption of the procedure. The surgeon can also temporarily disable the laser from firing at any point during the course of the surgery via suitable manual controls.

0 The tracking subsystem of the invention serves two important purposes: it tracks and follows the movements of the patient's tissue -- not only the voluntary movements which can be damped with specialized treatment, but also the involuntary movements which are more difficult to control on a living specimen -- and continuously re-presents an image
5 of the same section of tissue. Thus the surgeon/user is provided a continuous, substantially immobilized view of that tissue regardless of patient movements; and it further provides a fail-safe means for immediately stopping the action of the surgical laser beam in the event the tracking is lost, i.e., the tissue is not recognized by the tracking algorithm following
10 the motion, per the discussion on safety features above.

In accordance with the invention, fast imaging and tracking are achieved using the combined effects of a pivoting tracking mirror which may be under the directional control of a piezoelectric or electromagnetic
25 transducer, or other rapid servo device to pursue eye motions in a plane perpendicular to the optical axis of the final focusing lens (also referred

to herein as the X-Y plane), coupled with a motor drive which translates the otherwise fixed final focussing lens assembly along the axial direction of the final focussing lens, herein denoted as the Z axis. Thus, three dimensional motions which fall within the domain of capture of the tracking system can be observed, pursued and captured.

Fast response times are possible with the described embodiment of the invention, limited by the ultimate speed of the tracking detector, the computational capabilities of the apparatus microprocessors and data transfer rates, and the moment of inertia of the tracking servo mirror. It has been determined that such closed loop target recognition and tracking should occur at least at a rate of approximately 20-to-40 Hz in order to compensate for involuntary eye motion and thus provide a significant improvement over human reaction times. Tracking rates on the order of 100 Hz for full amplitudes on the order of $\geq 1\text{mm}$ (about 5°) in the transverse direction and in excess of 40Hz over a range of $\pm 2\text{mm}$ axially, would ultimately be achievable with some improvements based on the methods and system of the present system.

In a preferred embodiment of the present invention, the tracking sensors, or detectors, in combination with their circuitry, should be capable of high spatial resolution. Examples are linear position sensing detectors and quadrant detectors. For corneal refractive surgery, the limbus of the eye provides a landmark ideally suited for such detectors. In the retina, landmarks such as the optic disk, or vessel configurations can similarly provide landmarks upon which a magnified view can serve as the track-

ing landmark. In the present invention, any natural eye feature located in proximity of and structurally contiguous to the target site will serve as the tracking landmark. The important observation is that the location of the tracking landmark must respond to forces and pressures in a manner similar to the targeted tissues, yet it cannot be coincident with the precise target site itself, since this site will change during the course of the surgery.

Since the limbus is the outer edge of the cornea, it is expected that the limbus will respond to changes in position in a similar manner to other corneal tissues. The limbus further has the advantage of being contiguous to the sclera. Correspondingly, it is expected that the transient displacements occasioned by the impact of the laser pulse on the target site will be damped sufficiently at the limbus so as to not induce fictitious tracking signals. Such fictitious tracking signals would normally be a frequent observation if the present invention were to use, for example, a mark on the surface of the cornea in the vicinity of the operative site or a remote symmetry axis. Similar considerations apply when selecting a tracking landmark in other eye segments.

By incorporating intensified cameras, the present instrument and system is of high sensitivity, requiring only low levels of illumination, and produces video images of high contrast and high resolution. Illumination levels are kept well within established safety levels for the human eye. With the optics of the present system the patient's tissue is observed from an appreciable distance, sufficient for comfort to the patient

even during eye surgery, and sufficient to permit the surgeon/user ready access to the patient in case of emergency, to insure safety at all times, to reassure the patient, or for any other reason which the surgeon/user may feel justifiable.

Zoom optics are included so that the physician can select a range of magnification for the video image, which may be from about, say, 15X to 200X. Different zooming ranges may be appropriate for different types of surgical procedures while maintaining an overall zooming capability of approximately 15-fold. The viewing system may be refocused in depth as well as transversely, independent of the treatment beam, as desired.

In one embodiment of the present invention, a system for use in ophthalmic laser surgery includes a laser source with sufficient output power to effect a desired type of surgery in the ocular tissues, along with an optical path means for delivering the laser beam, including beam directing and focussing means for controlling the aim and depth of focus of the laser beam. In a preferred embodiment of the present invention, a laser firing up to 250 shots per second is employed. Such a laser device can generate an intricate pattern consisting of 50,000 shots aimed separately at different locations in under 4 minutes. For most types of ophthalmic surgery procedures falling in the domain of application for the system disclosed herein, the method of deposition of the laser pulse energy onto the target site calls for achieving irradiances at the target site above the threshold for ionization of molecules within the target site and giving rise to an avalanche process culminating in plasma formation.

Since the maximal diameter of the lesion will consequently not be determined by the theoretical spot size of the laser beam but by the maximal outward expansion of the cavitation induced during plasma collapse, and since the maximal lesion capacity of the plasma is related to the amount of energy transferred into the plasma volume (and subsequently into a shock wave) by the laser pulse, considerable attention is needed to maintain the laser pulse energy within narrow variation tolerances. In one preferred embodiment of the present invention this is achieved by a closed feedback loop, wherein each laser pulse emitted by the system is sampled to determine the actual energy being emitted. Any trends in emission energy can thus be identified allowing subsequent emitted pulse energies to be adjusted accordingly.

U.S. Food and Drug Agency regulations for medical laser devices currently require manufacturers of said devices to provide a means for measuring the output delivered to the human body to within an accuracy of plus or minus 20%. There is no specification on emission tolerances for the lasers beyond the constraints of safety and efficacy. However, verification of average pulse emission does not preclude 50% variations between consecutive pulses in a firing sequence. Such variation range is one of the reasons why "missfires" occur in many ophthalmic devices. It is not that the laser failed to fire, but that insufficient energy was emitted to achieve the desired or expected result because of unforeseen and undetected energy variations. For an automated system such as the present invention, the emission from the laser needs to be monitored and adjusted to achieve far narrower pulse-to-pulse error tolerances.

In summary, it is among the objects of the present invention to greatly improve the accuracy, speed, range, reliability, versatility, safety, and efficacy of laser surgery, particularly ophthalmic surgery, by a system and instrument which continuously presents information to the surgeon/user during surgery as to the precise location, aim, and depth of the surgical laser and also as to surrounding features of the subject tissue, in three dimensions. It is also an object of the invention to track movements of the subject tissue during surgery, particularly critical in eye surgery where eye movements can be very rapid and involuntary. It is further an object of the invention to provide a safe means of first establishing a reproducible firing sequence positioned in a three dimensional space, and then firing the sequence at high repetition rates, thus obviating the time-consuming need to repetitively inspect, aim, and fire each shot before proceeding to the next target. Still another object is to provide a system applicable to non-medical fields wherein a laser beam is used to effect a precise operation on a target or series of targets subject to movement during the procedure. These and other objects, advantages, and features of the invention will be apparent from the following description of preferred embodiments, considered along with the accompanying drawings.

Description of the Drawings

Figure 1 is a block diagram of an instrument or workstation for performing precision laser surgery in accordance with the principles of

the invention. In Figure 1 the workstation is configured for ophthalmic surgery.

5 Figure 2 is a block diagram of the instrument or workstation indicating the path of the laser energy pulse as it propagates through the system along with the functions of control and information flow among various optical components, detectors, and controllers for monitoring the energy of the laser pulse and maintaining the emission within prescribed narrow error tolerances.

Figure 3 is a block diagram of the path for light traveling from and back to the depth ranging or Z-plane tracking means, together with the loop for information flow to the computer cocontrol means and back to the position means.

Figure 4 is the block diagram showing the light path from the parallax ranging assembly to the eye and the control path from the imaging video camera to the video monitor display means. The light path from the eye back to the imaging camera is also indicated in this Figure.

Figure 5 is a block diagram of the workstation in which the light paths and control loops for the X-Y place tracking means are shown.

25 Figure 5A shows the image of the iris incident on the two quadrant detectors used in a preferred embodiment of the sensor for X-Y tracking.

Figure 6 is a block diagram indicating the interplay of the imaging means with the video monitor display.

Figure 7 is another block diagram indicating the light path between the topography assembly and the eye together with the control loop and interface with the video monitor display. The displays generated by the topography loop depicted in this Figure are overlayed over the live image shown in Figure 7 by the computer control assembly.

Figure 8 is a scale drawing of one embodiment of the instrument of present invention.

Figure 9a through 9c represent three perspectives of an artistic rendition of an ergonomic configuration of the workstation. The system was designed to accomodate the engineering subassemblies in a maximally compact manner while providing a large amount of clear space for the patient.

Figure 10 is a detailed block diagram illustrating the functional interdependence among the various optical subsystems.

Figure 11 is a block diagram showing the sequence of control and information flow from the user interface elements to the firing of the laser.

Figure 12 is a photograph of a user interface screen showing a selection of computer generated patterns which can further be modified using "CAD/CAM-like" editing functions, such as are contained in a "utilities" module.

Figure 13 is an illustration of a user interface screen showing a window of a sample "treatment" menu used to select treatment eye segments, set lesion shapes, choose operating parameters corresponding to the template designated procedure and other functions.

Figure 14 is a photograph showing the same sample template as Figure 12, and highlighting an example of a pull-down "set parameters" menu.

5 Figure 15 is a topographical representation of a three dimensional eye surface as seen from the user/interface screen, highlighting a sample "diagnostics" module.

Description of Preferred Embodiments

15 In the drawings, Figure 1 shows a block diagram for the fundamental assemblies of a complete precision laser surgery and/or diagnostic/analytical instrument 10 in accordance with the principles of the present invention, in the form of a workstation. Not shown are the support station housing the video monitor means, the power supplies, the fire-control/safety switch and other accessories for the workstation.

Although the system, apparatus and method of the invention are illustrated and discussed with reference to ophthalmic surgery and diagnosis, it should be understood that the invention encompasses other types of medical diagnostic and surgical procedures, as well as non-medical operations (e.g. semiconductor processing, such as precision wafer fabrication, short repair using lasers and other micromachining techniques).

The instrument and system 10 of the invention include controls 16 for a vision system and laser firing, enabling the surgeon/user to survey the topography and internal features of the tissue to be operated upon (the eye in the illustrated workstation) via a video means 19, and, via the computerized control means, to precisely control the timing as well as the direction, depth and spatial pattern of firing of a laser beam in three dimensions. As will be explained below, the surgeon may control the firing of the laser with "templates" which can be superimposed over an image of the tissue being operated upon, and which enable an automatic tracing of a desired laser firing pattern based upon prior experience or a surgeon's insights with similar surgical procedures. The templates may be pre-programmed or generated anew for each patient, as the case requires.

The system also includes a final objective lens or focussing lens or front lens 17 (an element of the microscope assembly, as explained below), through which images are taken and through which the laser beam is directed at the subject tissue. In a preferred embodiment of the system, an axial illuminating light beam may be projected at the tissue through

the topography assembly 98 and the final objective lens 17. In other embodiments of the present invention, an off-axis slit illuminator, providing a ribbon-shaped illuminating light beam, may be used to augment and/or replace the axial illumination technique, (see Howland et al., Noninvasive
5 Assessment of the Visual System Topical Meeting, Santa Fe, Feb 4-7, 1991) depending on the particular kind of surgical procedure and error tolerances required thereof. The instrument 10 may contain, in addition, the therapeutic laser, 87, the surgical microscope, 86, an X-Y tracking assembly, 85, a depth ranging microscope, 84, a parallax depth ranging
0 assembly, 82, various illuminators, and the beam steering and focussing assembly, 81. All of these assemblies share an optical path defined by the final tracking mirror 72 and the lens 17.

The tracking mirror 72 represents a key element in the system, in
5 that it is in the path of light (whether transmitted or reflected), generated and/or acquired by all the various subassemblies of the workstation, excepting only the slit illuminator (of the alternate embodiment, not shown in Figure 1). In alternate embodiments of the invention, the tracking mirror may be driven either piezoelectrically or electromagnetically.
10 A piezoelectric driver uses the change in shape of a quartz crystal in response to a electric current to move the mirror. An electromagnetic driver uses a coil of wire in a magnetic field which is made to move by passing an electric current through the coil. The electromagnetic driver is similar in function to a voice coil of an audio speaker. In either embodi-
25 ment the speed (or, more accurately, the acceleration) of the entire

tracking system is limited by the response of the drivers and the mirror's moment of inertia.

5 Most of the major components and subassemblies, shown in the block diagram of Figure 1, are disclosed separately and have been incorporated herein by reference. However, the combination of these separate inventions into system 10, the methods by which they can be made to work in concert as an integrated unit, and the enhanced capabilities this entails in a surgical environment are the subject of the present invention.

For example, the topography technique requires establishing precisely the distance from the surface to be measured to the appropriate principal plane of the front focussing lens. Whereas there are several methods for establishing said distance, the modified confocal technique described by Fountain (copending U.S. Patent Application Serial No. 655,919) represents a preferred embodiment of such a measuring technique, incorporated by reference into the present invention. Since in surgery the targets are live tissue and are continuously in motion, to achieve high levels of accuracy requires that the surface to be measured by way of the topography assembly also remain stable with respect to the measuring sensors located within the topography assembly 98, the zoom video assembly 86, and the known focal point of the laser 87. This is achieved by continuously adjusting the position of the final focussing lens 17 along the axial direction as further described by Fountain (per above).

20

Figure 2 shows the light path 71 as it emerges from the laser 87, passes through the external energy regulator 83, is expanded and directed in the beam steering and focussing assembly 81 as further described by Fountain et. al. in copending U.S. patent application Serial No. 833,604 and is aimed via the tracking mirror 72 and through the front focussing lens 17 onto the prescribed target site. In a preferred embodiment of the invention, the tracking mirror 72 will have an optical coating which will permit a small portion of the laser energy to continue through the tracking mirror along the path 73 to be detected in the energy monitoring assembly 80, as depicted in Figure 2.

The pulse energy sensed in the energy monitoring assembly 80 is electronically relayed to the computer control assembly 16 which in turn analyzes the output energy from the laser 87 and adjusts the proportion of the laser energy of subsequent laser pulses to pass through the energy regulator 83. In an embodiment of the present invention, the energy regulator 83 is a polarizer adjusted to be "crossed" with the polarized laser pulse, preceded by a rotatable half-wave retardation plate. The energy monitor 80, consists of an integrating sphere and detector which can record energy on a pulse-by-pulse basis. The energy detector calculates weighted exponential moving averages, modified with a weighting factor, as well as the rate of change of the running average. The accuracy of measurement of the pulse energy is within 5%, based on calibration against standard energy meters (e.g., Molelectron, Scientech).

In a preferred embodiment of the system 10, the steering, focussing and aiming subassembly 81 may consist of a beam expander 22 that provides depth of focus variations through change of collimation, and a dual set of Risley prisms (also known as Herschel prisms) 21 to steer and aim the beam, as described in detail in U.S. patent application Serial No. 833,604

The beam expander may comprise a set of lenses 23, a stepper motor 41 and a slide 43, with 75 mm traverse corresponding to ~ 25 mm in the eye. Beam focus accuracy to within 10 um can be provided in this manner, based on standard optical components. The Risley prisms are selected as preferred means of beam steering and directing because of lower moment of inertia and shorter lever arm as compared to alternatives, such as gimbaled mirrors. The lower moment of inertia inherently allows faster aiming (which is enhanced by the use of cylindrical coordinates, these being more natural for the eye than Cartesian coordinates), while the shorter lever arm permits aiming further off-axis without beam-clipping (vignetting) at the aperture of the objective lens 17.

In a preferred embodiment of the invention, the surgical laser 87 emits radiation in the visible wavelength range to take advantage of the transmission properties of visible light in the optically clear tissues of the human eye. One preferred embodiment of the invention uses a frequency doubled Nd:YAG laser, producing sufficiently short duration pulses (shorter than a few hundred nanoseconds, and preferably shorter than 10 nanoseconds) to limit the amount of energy required to ionize material as discussed further below.

In alternative embodiments, the laser 87 may be one of several types of flashlamp- or diode-pumped solid state lasers (such as, Nd:YAG, Nd:YLF, Ho:YLF, Er:YAG, alexandrite, Ti:sapphire or others) operating in the fundamental or a frequency-multiplied mode, a semiconductor laser, or an argon, excimer, nitrogen, dye, or any of a host of different lasers, or combinations thereof, currently available or in development. The present invention can be used with any of a wide variety of lasers by specifying different coatings where necessary for the optical surfaces. A quartz and magnesium fluoride focusing element is available as the element 17 to accommodate ultraviolet lasers whether they be excimer lasers or frequency shifted solid state lasers. One of the features of the present invention is that it is not laser specific, but represents a surgical instrument intended to enhance the efficacy of any therapeutic laser. The laser 87 preferably produces a pulsed beam which is controllable as to the level of energy per pulse, pulse peak power, and repetition rate. For ophthalmic applications which do not seek to generate laser lesions below the front surface of the cornea, or wherever incising the eye is an acceptable option as a preliminary or as part of the procedure, then excimer lasers, holmium lasers, carbon dioxide lasers or some other ultraviolet or infrared laser may be an acceptable modality. In one embodiment of the present invention, the surgeon is not restricted to surface effects or to incising the eye. With the same visible wavelength laser (for example, a frequency doubled Nd:YAG), the surgeon can select any tissue depth (whether on the corneal surface or below, whether on the posterior lens capsule or in the lens nucleus) at which to generate an effect without the necessity of exchanging laser modalities for different eye segments, provided there

remains an optically clear path to the targeted layer in the corresponding visible range.

In the event a non-visible-wavelength laser beam is used (e.g. strictly for ablating the front surface of the cornea, or strictly for coagulating blood vessels in the retina, or strictly for photodisrupting membranes on the posterior capsule) some variations in the optical configuration of the system 10 will likely be required.

Figure 3 shows the information path for the depth ranger assembly 84 that measures the distance from the front focussing lens 17 to the surface of the eye 69 and continuously adjusts the position of the front focussing lens 17 along a path 88. In a preferred embodiment of the present invention, the path length 88 over which the front focussing lens is adjusted is 5 mm. The system comprising subassembly 84 together with lens 17 and the intervening optics, is sometimes referred to herein as the confocal microscope. It uses optical elements in common with the other equipment in the system 10, namely the tracking servo mirror 72 and the beam splitters 65 and 66. The focusing lens 17 is adjusted as to focus, along a Z axis, in response to shifts in the depth of the subject tissue feature, so that the system always returns to a focus on the corneal vertex 56 (the part of the cornea that is closest to the objective lens).

Included in the depth ranger assembly 84 are depth tracking or "Z-axis" tracking sensors 50 which detect a change in location of the surface 69 as described by Fountain in a copending U.S. patent application (Serial

No. 655,919, incorporated by reference herein) and relay the information to the computer control assembly 16 which computes a new desired position for the front objective lens assembly 17 and issues instruction to a motor drive to relocate said lens assembly 17 to the desired new position.

- 5 A closed loop is thus described which incorporates the live movements of the eye surface within the decision process of adjusting the focal point of lens assembly 17, to within given tolerances. In this embodiment, the capture range for axial acquisition is within ± 0.2 mm and tracking rates in excess of 40 Hz are within the servo loop capability for maximum
0 ranges on the order of 2 mm.

- Since mirrors and beamsplitters 64, 68, and 72, together with beam splitting cubes 65, 66, and 67, link the other assemblies of the system 10 into a common axial path passing through lens focussing assembly 17,
5 they can all be referenced to the lens assembly 17 as if the distance between lens 17 and eye surface 69 were to remain constant. This is a major simplification in the manner in which eye surgery can be performed in that the surgeon need no longer be continuously monitoring eye movement to verify a constantly changing focal position within the patient's eye.

- For procedures where the targeted tissue layers lie posterior to the cornea, the surgeon/user will have the use of the parallax depth ranging instrument 88 as shown in Figure 4. This assembly relies on the intersection of two beams of light (from, e.g., a He-Ne illuminator laser) converg-
25 ing to a common point on a given surface. In one embodiment, the parallax ranger allows mapping of a mesh of points, acquired through judicious

adjustment of the zoom camera to short depth-of-focus (maximum magnification), which, along with corresponding variation of the focus on the parallax ranger, produces a series of diffraction limited spots on the structures behind the cornea (iris, lens, etc.). In this manner, the resulting surface will define a desired template.

The inclusion of a parallax ranger within the instrument 10 overcomes difficulties commonly associated with specular reflection techniques used for detection of the location and measurement of ocular features. Basically, only the tear surface layer overlying the corneal surface epithelium is usually detectable and measurable by specular light reflection techniques. The reflected light signal is generally insufficient for the extraction of topographic information of the endothelium surface of the cornea (<0.02% reflection versus 4% from the epithelium), let alone for characterization of the three dimensional shape of the anterior and posterior capsules of the crystalline lens of the human eye. The parallax ranger unit provides the surgeon/user with the option of using a combination of standard techniques which rely on images of a target site. Thus, the surgeon/user can identify, to within the inherent error tolerances of the technique, when the instrument is focussed on a given surface. The precise focal point of the beam can then be varied by altering the incoming beam divergence by way of defocussing a beam expander means 22 (included within assembly 81). By redefining the origin of a given procedure to coincide with the depth at which the parallax ranger is focussed on a surface, this new identified surface becomes the reference surface for performing a surgical procedure. Via the user interface (See Sklar et. al., U.S. patent

applications Serial Nos. 307,815 and 475,657, incorporated by reference herein), the surgeon/user can then define lesion templates or configurations to be performed at a given depth with respect to the new identified surface.

Similarly, the motion of the eye along a plane perpendicular to the Z-axis of the front focussing lens assembly 17 also needs to be stabilized. This is achieved using the X-Y tracking path shown in Figure 5. Intrinsic to any tracking scheme is the choice of what is to be tracked. If the eye were
0 a non-deformable body, then any landmark on or in the eye would suffice for defining the motion of said material. However, the eye neither moves nor deforms as a rigid body. Consequently, in order to define the location of a moving tissue layer within the eye, the tracking landmark must be located contiguous to the targeted tissue and should mechanically respond
5 in a manner similar to the targeted tissue.

For corneal refractive surgery, the eye limbus at the radially outward edge of the cornea satisfies these constraints. It has the advantage of not only moving with the cornea -- inasmuch as it is a part of the cornea -- but, since it likewise is connected to the sclera, it will not respond
20 as dramatically to the transient deformations associated with the microsurgery. In effect, pursuing the motions of the limbus will allow the computerized control system to replicate the template pattern presented on the display by the user interface, even though the eye surface will be
25 appreciably deforming during the course of the surgical procedure.

In one embodiment of the invention, the transverse X-Y tracking detector consists of high speed quadrant detectors and a microprocessor such that updated position information is fed to the tracking mirror at frequencies substantially higher than the repetition rate of the laser, or the frame rate of the imaging camera. The response time of the tracking detector and processor should be sufficiently faster than the maximum repetition rate of the laser, so that laser firing can be disabled, if necessary. The response time of the detector and processor should also be higher than that of the driven tracking mirror, which must be capable of sufficiently high acceleration and velocity to compensate for the fastest motion possible by the intended target.

In Figure 5, light from the limbus 70 passes through the objective lens assembly 17, is reflected by the X-Y tracking mirror assembly 72, and is propagated via the beam splitting cubes 65 and 66 through the viewing lens 63 to be reflected off beam splitter 67 to the sensors of the X-Y tracking assembly 85. In one preferred embodiment of the present invention, a spatially sensitive sensor 50 comprising two quadrant detectors is used to track an image of the outer rim (at the limbus) of the iris 32. As shown in Figure 5A, the image at the quadrant detectors (each with four quadrants, 35, in this example) will then consist of a bright lune-shaped field corresponding to the sclera 33, adjacent to a darker field representing an image of the iris, 32. The very dark central core which is an image of the pupil 34, is not captured by the detectors, as Figure 5A illustrates, leaving a single sharp boundary to track. With various cells of the quadrant detector connected through differential amplifiers and nor-

malized by the sum, the resultant signals are sensitive only to the position of the centroid of illumination of any of the above patterns. Quadrant detectors integrate the image illumination striking each quarter of the detector face. The luminosity impinging on the detector faces will then
5 generate voltage differences corresponding to the integrated differences in light hitting the detector parts. A change in background light intensity will be ignored, as the increase across the four (or eight) quadrants 35 of the detector face will remain the same. Voltage sums and differences among the quadrants serve to establish the relative direction of motion
0 between two contiguous readings of the limbus position. A shift in intensity at the sensor is thereby traced to motion of the limbus. These dedicated quadrant detectors record voltage changes extremely rapidly and can observe and quantify contrast changes and edge motions in less than 100 microseconds. In alternate embodiments, similarly fast but more sensitive
5 position sensing detectors are used in this application, yielding enhanced performance at even lower light levels.

The voltage change information is relayed to the computer control assembly 16 wherein the actual coordinate shift is calculated. Control
20 assembly 16 then determines the angular corrections to be relayed to the X-Y tracking mirror assembly 72 and activates a voice coil or other electromagnetic drive assembly to pivot the orientation of mirror 72 so as to stabilize the X-Y motion of the limbus 70 with respect to system 10. This embodiment of a tracking system uses entirely analog signals and techniques
25 to achieve tracking and can be made to work significantly more rapidly than even the fastest involuntary motions of the eye.

In one preferred embodiment of the invention, the range of use, or travel, is 2 millimeters in the X-Y plane. For ophthalmic applications, where the principal motions of the eye are rotations, it is often preferable to define the range of use in terms of angular sweep of the eye. For example, an angular motion of the eye of 5 degrees falls well within the domain of use of the X-Y tracking system. For a sighted human patient, it has been estimated that such range of use will acquire an eye looking at an image point located in the far field (relative to the patient) and situated along the optical axis of the apparatus.

The transducers of the tracking system adjust the position of the X-Y mirror along two rotational axes at accelerations on the target in excess of 20 microns per millisecond for full amplitudes of over 2 millimeters, based on microprocessor-provided information relating to the new location of the same tissue.

The eye surface 69 may be displaced in translation and/or by rotational motions centered on the globe of the eye; because the X-Y tracking mirror 72 rotates about a point within its assembly that is different from the eye's center of rotation, a desired change in X-Y tracking mirror position also requires a correction of the X-Y axis position of the depth ranging and tracking assembly 84. Consequently, the algorithm which pivots the X-Y tracking mirror 72 along paths 61 and 62, also must relay instructions to the computerized control system to adjust the depth tracking and ranging assembly 84 so as to maintain the correct orientation. The pre-

ferred methods to achieve this correction use a compensating mirror 60 within the Z-tracking assembly (not shown in Figure 5).

5 The tracking system system has the advantage of being able to find an absolute position on the target even after a temporary loss of tracking. For example, if a surgical procedure is in process and an obstacle, such as a blinking eyelid in many ophthalmic procedures, interposes the tracking image such that the procedure is interrupted or temporarily aborted, the tracking system will automatically store in memory the last position in
0 the firing sequence so that once the target is again reacquired, the exact location of the next point in the firing sequence can be determined automatically and the servo mirror be repositioned accordingly.

Figure 6 shows the surgical microscope loop. This subassembly includes the low-light-level camera and the zoom optics. The camera preferably comprises an intensified video camera, for example a silicon intensified target (SIT) tube camera. Alternatively it can be a conventional video camera in combination with a microchannel-plate intensifier. In
5 either event the camera's sensitivity preferably is about 1000 times that of a normal video camera, enabling the system to look at weakly scattered
10 light and targets poorly illuminated for the desired levels of high magnification at large working distances.

In a preferred embodiment of the present invention, the system uses
25 a combination of specular and scattered light techniques for detecting and identifying diffusely reflecting surfaces, specularly reflecting surfaces,

surface displacements, features, and shapes of the patient's tissue. This is particularly useful in the eye where it can prove difficult to differentiate between the amorphous tear layer anterior to the cornea and the structured epithelial surface layer of the cornea. Even the cell walls of the endothelial cells of the cornea or of the anterior lens capsule will scatter light. The intensified surgical microscope can produce an image of these actual cells by forming an image composed by detecting scattered light. The surgical microscope, as well as the tracking camera, can substantially exclude specularly reflected light by cross polarization of selectively polarized illuminators. Other methods for reducing specular reflections preferentially to scattered images are also possible.

The microscope optics are designed to provide flat field, anastigmatic, achromatic, nearly diffraction limited imaging with optical magnification zoomable approximately over a 15-fold range of, say, 15X - 200X. The magnification is adjustable and is typically selected to correspond to the largest magnification which can still be comfortably used for situating a lesion (that is, the smallest field of view which can be used when magnified across the fixed display size of the video monitor). For example, for corneal refractive surgery, where the surgeon needs to observe the cornea from limbus to limbus, this corresponds to a field of view of approximately 12 to 14 millimeters. At the screen, the zoom optics allow for adjustable magnification in the range of about 15X to 200X, for example. This enables the surgeon to view a very narrow field, on the order of a millimeter in width, or a much wider field at lesser magnification. This is useful in enabling the surgeon to assure himself that he is aimed and

focused at a particular desired region. Zooming can be effected through use of a joystick, trackball, mouse, or other pointing device 42 to access a scroll bar in the user interface.

5 The function of the viewing mirror 68 shown in Figure 6 is to move the surgical microscope image on the screen to the left or right or up or down, independent of the aiming of any other subsystem.

Figure 7 shows the light path for the topography assembly 98,
0 which provides a three dimensional mapping system directed at the surface of the target, e.g. the eye of the patient. In a preferred embodiment of the system 10 (as described by Sklar in U.S. patent No. 5,054,907 and further extended by McMillan and Sklar in copending U.S. patent application Serial No. 656,722 and by McMillan et. al. in copending U.S. patent applica-
5 tion Serial No. _____, per ref. No. 266P cited above, all of which are incorporated herein by reference), the subassembly 98 may comprise a light projector 95 including an internal profilometry source 90, an illumination mask 96, an optical collection system 94 and a profilometry assembly consisting of, e.g., an adjustable aperture 99 and a CCD camera 97
20 equipped with a frame grabber. In one preferred embodiment of the invention, the light projector 95, using the profilometry source 90, projects a predetermined pattern, such as an array of dots arranged into rings and radial spokes converging to a common center, onto the tear layer of the eye. The reflected images of the predetermined pattern are collected by
25 the optical assembly 94, which may include a set of plates to correct for any astigmatism induced by the tracking mirror 72 and any other interior

mirrors, fed into the profilometer camera 97 through the aperture 99 for analysis. By controlling the angle of acceptance of the light bundle from each virtual image, the adjustable aperture acts as a spatial filter, providing a physical representation of the source of paraxial rays through trade-offs between resolution and brightness. The camera includes means to digitize and electronically enhance the images. The signals are fed to a microprocessor which performs preliminary displacement analysis using software means (embedded within the controller 16) based on mathematical morphological transformations as described by McMillan and Sklar (copending U.S. patent application Serial No. 656,722). The transformations comprise a solution of a set of coupled differential equations, whereby the local normals and curvature parameters are computed at each data point so that the surface can be computed to within the measurement accuracy, and subsequently displayed on the video screen 20. The methods of light projection and profilometry permit the system 10 to operate with low intensity light signals to enhance safety and patient comfort while extracting significant signal levels from the noise background.

In other embodiments of the profilometry assembly, alternative projection techniques may be utilized in place of or in addition to the mapping and projection means described above. In one embodiment, an external profilometry source 89, consisting of an array of LED's projects a pattern of dots onto the eye in a manner described by McMillan et. al. in copending U.S. patent application Serial No. _____, ~~ometry Technique Using Extended, External Light Sources~~ and referenced above as 266P. In this embodiment, curvature measurements of the anteri-

or surface of the cornea can be obtained extending up to 8 mm in diameter around the center. Other techniques based on off-axis illumination may utilize, e.g., a slit lamp illuminator 77 to obtain measurements of the thickness of the cornea, the depth of the anterior chamber and/or the thickness of the lens (the latter coupled with standard keratometry methods to correct for corneal curvature). Mounting the slit lamp at a fixed location relative to a CCD camera (such as 97) and rotating the entire structure around a center axis would also provide a method to collect global corneal data (out to the limbus) yet without sacrificing local accuracies, given the simultaneous 3D tracking capability already contained in the system. In this manner, the domain of topographic measurements can be extended from limbus to limbus while providing pachymetry data as well. Alternatively, topography methods based on Ronchi grating in conjunction with Moire interferometry, or advanced holographic techniques as discussed by e.g., Varner (in Holographic Nondestructive Testing, Academic Press, New York, 1974, pp.105) and by Bores (in Proceedings of Ophthalmic Technologies, SPIE Vol. 1423, C.A. Puliafito, ed., pp. 28, 1991) may be utilized in future embodiments of the system 10, if warranted for specific interventions.

Figure 8 is a schematic optical layout of a preferred system of optics for the instrument of the invention. In Figure 8, a Schneider Cinelux Ultra 90-mm focal length f/2 lens is combined with a Schneider Tele-Xenar 360-mm focal length f/5.6 lens, matching conjugates to form a 4X/0.24 numerical aperture (N.A.) "objective lens" 17 with a working distance of 59 mm. This type of design embodies a key feature of the

present invention, whereby a comfortable distance between the patient and the optics is implemented (sufficient to provide the surgeon/user enough open clear space to easily fit his hands between the front "objective lens" 17 and the patient's eye/target surface 69) while maximizing the aperture ratio of the system. A beam splitter between the front and back lenses of this "objective lens" allows the 90-mm lens to also serve as the final focusing lens for the laser. A Schneider Xenon f/2 lens, with 28-mm focal length, relays the image to the camera contained within subassembly 86, with magnifications zoomable from about 0.4X -5.4X in this embodiment of the invention. An appropriate field lens 58 is used to provide uniform illumination across the image of the maximum 15-mm field of view at the object (eye) and to reduce the magnification. Zooming can be accomplished by computed-and-stepped motions of both the zoom lens 59 and the camera. The total optical magnification is thus zoomable in this embodiment from about 0.8 to 11. With the image incident on a 2/3-inch video detector and displayed on a thirteen-inch (diagonal) monitor, an additional 19X video magnification is gained, thus a maximum magnification from the target to the screen of about 200X is achieved.

Another important feature of the optics of the system of the invention is that the servo tracking mirror 72 actually is positioned inside the "objective lens" assembly (the final element has been designed to have sufficient field to accommodate the small misalignments caused by the tracking mirror). This enables the system to achieve rapid tracking of ocular features (or other tissue features) in an efficient and relatively

simple assembly, without moving an entire objective lens in following the sometimes rapidly moving features.

The optical system is designed without correction for the aberrations of the eye. For work in the cornea no corrections are needed. For work at image planes located posteriorly to the cornea, such as the retina, for example, contact lenses 28 (e.g., Goldman or similar) may be used, as shown in Inset a of Figure 8.

As illustrated in Figure 8, the illuminator light beam contained within assembly 82, first is reflected off a turning mirror 73, then transmitted through mirror 64, to join substantially coaxially with the path of the laser beam along the beam axis 71 (see Figure 2). Both beams are then steered through the beam steering and aiming optics in assembly 81 and are reflected off a reflective surface in the polarizing beam splitter 65 before being incident the tracking mirror 72. The polarizing beam splitter 65 (along with beam splitter 67) effectively prevent internal back reflections of the laser pulses from the optics of the system from damaging or overwhelming the sensitive video microscope camera contained in assembly 86.

Also indicated in Figure 8 are the optical tracking and viewing elements namely, the depth ranging assembly 84, the X-Y tracking assembly 85, and the surgical microscope 86, all share the same optical path from beam splitter 66 to the eye. Some key design details of the Z-tracking assembly 84, including the illumination source (such as a red He-Ne laser)

are shown in Inset b. These are described in more detail in copending U.S. patent application Serial No. 655,919.

As Figure 8 shows, the beams generated by the therapeutic laser 87 and the parallax ranger 82 are coaxial with each other, but the axis of these beams is not necessarily coaxial with the axis of view of the profilometer camera 97, the topography illumination source 90 or the other tracking/viewing assemblies 84, 85 and 86. This is because of directional steering Risley-prism sets 21 embedded within assembly 81 which are outside the optical path of assemblies 84, 85 and 86 but within the optical path of the parallax depth ranger 82 and the laser 87. The Risley prisms are steerable via the computerized control assembly 16 under the control of the surgeon/user through user interface commands. They provide means for adjusting about the X and Y axis, thus letting the physician select different locations for firing the laser as disclosed by Fountain and Knopp in copending U.S. patent application Serial No. 571,244. The two elements 82 and 87 therefore will only be coincident with the axis of view of the depth tracking assembly 84 when the surgeon aims the laser directly at the center of the field of view of assembly 84. In other instances they will share the same "optical path" via elements 72 and 17, but they will not be on identical axes. The Risley prisms within the assembly 81 allow movement of the actual aim of the therapeutic laser beam from the laser 87 to a real aiming point which is coincident with the computer-generated aiming points.

The set of beam expander lenses 23 preferably are positioned as close as practical to final objective lens 17, and are initially adjusted so as to expand the diameter of the laser pulse emerging from the laser cavity and collimate it so that a parallel but expanded beam of light emerges from the lens 22. The expanded, collimated beam is incident upon the final lens 17, and the expanded beam fills the lens to the extent compatible with vignetting for off-axis aiming. Thus, a large-diameter beam is focused by the lens 17, so that only at the point of focus within the eye is the diffraction limited pulsed laser beam effective in generating the desired therapeutic lesions in the eye. The depth of the focal point is varied by adjusting the distance between the two lenses 23, which has the effect of changing the degree of collimation and hence the focus as indicated explicitly in Figure 8. The surgeon's adjustments of the focus of the beam via the computerized control system 16, are superimposed on top of the automatic adjustments effected by the tracking system, and net focus changes are carried out by the system. This is easily accomplished using hardware and software associated with the system which does not in itself form a part of the present invention.

The decoupling of the aiming and viewing functions allows off-axis work, which represents a major improvement in the function of the system 10, in that off-axis capability is a mandatory feature for corneal and most other applications. Thus, an independent mirror 68 is inserted upstream of assembly 86 to allow viewing, while aiming is performed independently in the coaxial illumination path using the Risley prisms 21 of subassembly 81. In an alternative embodiment of the system disclosed

herein, a secondary angular steering mirror 60 (not explicitly shown in Figure 8) may be added in assembly 84, to compensate for motion imparted by the X-Y tracking mirror which can, for large enough eye motions, cause the Z-tracking system to "lose lock".

Inset c of Figure 8 shows some schematic detail of the external slit lamp illuminator, provided in an alternative embodiment of the system 10 to augment and/or replace the internal profilometry illumination source 90, and provide ocular thickness measurements as was described above (see discussion following Figure 7). The slit lamp constitutes the only element of the system not coaxial with the optical path defined by the tracking mirror 72 and the "objective lens" 17 common to all the other subassemblies.

Figures 9a, 9b and 9c show three perspectives of an ergonomic rendition of the workstation which incorporates the entire system 10. The system 10 in this illustrated embodiment of the invention is intended for ophthalmic surgery, with the patient to be seated, as shown in Figure 9a, in a chair 11 with his forehead against a forehead rest 12 and his chin against a chin rest 13 as shown in Figure 9b. Both forehead and chin rests are fully adjustable. The surgeon/user is free to stand at a convenient location where he/she can survey the progress of the surgery as depicted on the video monitor means 18 (containing the video display means 27,

including screen 20) as depicted in Figure 9c, while having direct access and observation of the patient, or to sit in a chair 14. The seats 11 and 14 for the patient and the surgeon, respectively, preferably are fully adjustable with e.g., tracks 15 (shown in Figure 9a) for adjusting proximity to the apparatus and with full height and seat back adjustability.

A hand held system control switch 24 in Figure 9a may be provided for the surgeon as a safety device which will both enable the laser triggering means when sufficient pressure is exerted on the device 20 (via a simple toggle switch, for example), or alternatively will immediately interrupt laser firing if pressure on the control means 24 is released.

Figure 10 is a functional block diagram showing the principal components and individual control and informational feedback functions of the precision laser surgery system of the invention, all indicated as being under control of a central processing computer 16, designed to integrate and control the operation of the entire system 10. The computer may include a microprocessor 140, software programs 141 and firmware 142 as indicated in Figure 10, as well as a number of other control and indicator features (not indicated) such as the enabling (or disabling) of internal safety interrupts, a light-emitting diode (LED) display which indicates when the tracking system and target acquisition system are operational and on-target, an LED which lights up when the system components have successfully been verified to be performing within system specification ranges, an LED indicating power is on, and a dedicated video display function to assist in detecting location of a system malfunction. Note that

some key functions in the system are carried through dedicated microprocessors 150, which, for simplicity, are shown in Figure 10 sharing the same block as the central microprocessor 140.

5 During the start-up phase of the system 10, a complete system verification is performed automatically without further prompting from the surgeon/user, including a set of internal diagnostics listing the status of operational use of the various assemblies. During this start-up phase, the assemblies shown in Figure 10 (and Figure 1) are each individually tested
0 for operational status within prescribed tolerances. If all tolerance levels are satisfied, the user interface screen 20 appears and the system is enabled for use. Additional safety LEDs acknowledge sufficient pressure on the laser fire safety interlock in the hand held (or, foot pedal) safety device 24, and whether the microprocessor generated template pattern is
5 in control of the firing sequence.

As shown in Figure 10, the central computer (which receives simultaneous diagnostic measurement and tracking information) closes each control loop through a central fire control function shown as block 100
20 forming a critical part of the computer control assembly 16. This fail-safe mechanism is a key feature provided within the instrument and system 10. Thus, the computer, which directly controls laser firing, as indicated by control line 144, automatically interrupts the firing sequence should any of the required operational specifications not be met (such as
25 loss of tracking, deviation of the pulse energy, etc.). If all preset conditions are met, the computer control assembly enables and fires the surgi-

cal laser in accordance with preselected templates shown, functionally, as block 6. The required information comprises confirmation that the template is still positioned correctly, i.e. that the targeted feature of the eye has been tracked within a preselected time allotted, so that the images of the eye remain stabilized. If this confirmation is not sent (or a contrary signal could be sent to signal that tracking is lost), the template controlled laser firing is immediately interrupted, as discussed in more detail below.

The user interface shown in a block 19 in Figure 10, communicates with the central computer unit 16 as indicated by control line 123, though it may also have some controls which do not involve the main microprocessor 140. Thus, if the surgeon wishes to generate a template for surgery, as shown in dashed line 131, or merely to change the display on the video screen for the purpose of selecting a different type of presentation, or for imposing a different surgical path on the screen, these communications are carried out through the central processor unit (CPU) 140 (taken to include appropriate software 141 and firmware 142), which controls the computer-generated images on the screen as well as most other functions in the system. As such, once the surgeon/user has finally determined his selection of template, has superposed that template using the computer controls 16 onto the positioning diagnostics at the desired location where the surgery is to be effected, and the modifications to the shape of the template have been effected to accommodate for the particular configuration of the patient as observed through the video display means 27 (which includes the screen 20) and the reconstructed target cross-